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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,277	12/21/2001	Timothy E. Benson	00481.CN1	3061

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	10/027,277	BENSON ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004 and 04 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *19-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 3/8/04 and 5/4/04, are acknowledged. Amended claims 2, 5, and 18 are acknowledged.

Applicant's arguments, filed 3/8/04 and 5/4/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The information disclosure statement, filed 9/5/03, has been fully considered.

The information disclosure statement, filed 3/8/04, fails to comply with the provisions of 37 CFR 1.97, 1.98, and MPEP § 609, because reference "BLAST 2 Sequences" lacks a publication date on the actual copy. It has been placed in the application file and looked at by the Examiner, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609, ¶ C(1).

Claims 1-18 are herein under examination.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The provisional rejection of claims 1-18 is maintained under 35 U.S.C. 101 as claiming the same invention as that of claims 54-71 of copending Application No. 10/028224.

This rejection is reiterated and maintained for reasons of record.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1-18 is maintained under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/144441.

This rejection is reiterated and maintained for reasons of record.

Application 10/144441 discloses a method for crystallizing a human beta secretase molecule or molecular complex in claims 1-23. While the scope of claim 1 of Application 10/144441 differs from instant claim 1 with the addition of crystallizing the human beta secretase molecule or molecular complex (claim 1, line 5 of Application 10/144441) as well as stating the solution comprises of purified human beta secretase and the inhibitor with a pH of at most about 6.0 (claim 1, lines 6-7 of Application 10/144441), there is significant overlap between this claim of Application 10/144441 and the instant claim 1 as both methods crystallize a human secretase molecule or molecular complex which encompass similar inventions. The pH stated in instant claim 1 is also stated in claim 4 of Application 10/144441. Claims 1-18 of the instant application and claims 1-23 Application 10/144441 have differing scopes but contain significant overlap with minor obvious variations which suggests an obviousness-type double patenting issue.

This is a provisional obviousness-type double patenting rejection.

The provisional rejection of claims 1-5, 7-8, and 10-14 is maintained under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-23 and 25-26 of copending Application No. 10/143723.

This rejection is reiterated and maintained for reasons of record.

Application 10/143723 discloses a method for crystallizing a human BACE molecule or molecular complex in claims 12-23 and 25-26. Human BACE molecule as stated in claim 12 of Application 10/143723 is also known as human beta secretase as stated in the instant claim 1. While the scope of claim 1 of Application 10/143723 differs from instant claim 1 with the words "potential modifier" (claim 12, line 3 of Application 10/143723) which can mean an inhibitor or enhancer as well as stating the solution comprises human BACE and the modifier with a pH of 4.5 to 5.6 (claim 12, lines 5-7 of Application 10/143723), there is significant overlap between this claim and the instant claim 1 as both methods crystallize a human secretase molecule or molecular complex which encompass similar inventions. Overall, claims 1-5, 7-8, and 10-14 of the instant application and claims 12-23 and 25-26 of Application 10/143723 have differing scopes but contain significant overlap with minor obvious variations which suggests an obviousness-type double patenting issue.

This is a provisional obviousness-type double patenting rejection.

The provisional rejection of claims 1-8 and 10-16 is maintained under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-15 and 17-23 of copending Application No. 10/143502.

This rejection is maintained and reiterated for reasons of record.

Application 10/143502 discloses a method for crystallizing a human beta secretase molecule or molecular complex in claims 7-15 and 17-23. While the scope of claim 7 of Application 10/143502 differs from instant claim 1 with the words "potential modifier" (claim 1, lines 3-4 of Application 10/143502) which can mean an inhibitor or

enhancer as well as stating the solution with a slightly different pH of 3.5 to 5.6 (claim 7, lines 5-6 of Application 10/143502), there is significant overlap between this claim and the instant claim 1 as both methods crystallize a human secretase molecule or molecular complex which encompass similar inventions. Overall, claims 1-8 and 10-16 of the instant application and claims 7-15 and 17-23 of Application 10/143502 have differing scopes but contain significant overlap with minor obvious variations which suggests an obviousness-type double patenting issue.

This is a provisional obviousness-type double patenting rejection.

Applicants state that upon indication of otherwise allowable subject matter and in the event these rejections are maintained, Applicants will provide an appropriate response. As these issues have not been resolved, these provisional rejections are maintained.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue

experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF SCOPE OF ENABLEMENT

The rejection of claims 1-18 is maintained under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is reiterated and maintained for reasons of record.

Although Applicants have disclosed information to enable one skilled in the art to make the trigonal space group $P3_221$ crystals of human beta secretase with (hexagonal shaped unit cells, page 6, lines 9-10) unit cell dimensions a =112.0 ± 35 Å, b = 112 ± 35 Å, c = 110 ± 35 Å, $\alpha = \beta = 90°$, $\gamma = 120°$; and space group $P32_21$ with cell constants a = 99.4 ± 35 Å, b = 99.4 ± 35 Å; c = 117 ± 35 Å; $\alpha = \beta = 90°$, $\gamma = 120°$; the specification does not reasonably provide enablement for crystallizing other human beta secretase molecules or molecular complexes as stated in claim 1. The claim is broader than the enablement provided by the disclosure with regard to the large number of possible crystalline helicases that could be made. As the science of protein crystallization is well known to be a trial and error procedure with unpredictable results (Drenth, page 1, lines

13-20), one skilled in the art would require clear and precise guidance to make any particular crystal. Accordingly, it would be very difficult for a skilled artisan to make crystal structures of other crystalline human beta secretases or co-complexes beyond those mentioned in the instant case where specific coordinates are disclosed. Due to the unpredictability and difficulty of crystallizing proteins, it is unlikely that one of skill in the art would be able to make another crystal relying solely on the information for the crystals disclosed in the specification without undue experimentation. Also, the information provided in the Examples section, pages 33-44, does not sufficiently enable a skilled artisan to make compositions comprising crystalline human beta secretase as no specific chemical entities or ligands were mentioned. Again, due to the unpredictability in the art, a skilled artisan could not reasonably expect to make other human beta secretase crystallines or co-crystalline complexes based on generic guidelines without undue experimentation.

Applicants submit that the Examiner has failed to establish a prima facie case for the lack of enablement in accordance with M.P.E.P. § 2164.04. It is noted that this rejection is a lack of scope of enablement, not a lack of enablement rejection. Certain material described above is enabled. Applicants' statement is found unpersuasive as the Examiner has established a reasonable basis to question the enablement. The Examiner has cited the Drenth article above which describes the unpredictability in the protein crystallization science. In addition, as stated in the MPEP 2164.03:

The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling.

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), stated:

[I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof.

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. In re Vickers, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); In re Cook, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d

1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

As it is not readily apparent that other species will work in this unpredictable protein crystallization science, this lack of scope of enablement is maintained.

LACK OF WRITTEN DESCRIPTION

The rejection of claims 1-18 is maintained under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained and reiterated for reasons of record.

Claims 1-18 are directed to crystallizing a human beta secretase molecule or molecular complex. There is no disclosure regarding any crystals other than the trigonal space group $P3_221$ crystals of human beta secretase with unit cell dimensions a =112.0 ± 35 Å, b = 112 ± 35 Å, c = 110 ± 35 Å, $\alpha = \beta = 90°$, $\gamma = 120°$; and space group $P32_21$ with cell constants a = 99.4 ± 35 Å, b = 99.4 ± 35 Å; c = 117 ± 35 Å; $\alpha = \beta = 90°$, $\gamma = 120°$. As written, the claim may contain other crystals in the method that do not meet the written description provision of 35 USC 112, first paragraph. Applicants have not sufficiently described other crystals and compositions in such full, clear, and concise terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicants state that the instant invention is directed to crystallization methods, not crystals, *per se*. This statement is acknowledged; however, the method involves the act of making a crystal and the only crystals that have adequate written support in the specification as have being made (and thus Applicants had possession of in the invention) are the ones listed in the paragraph above. Meanwhile, the claims are broadly and reasonably interpreted to include the crystallization of other human beta secretase crystals with other space groups and cell dimensions which lack written support. Therefore, the lack of written description rejection is maintained.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 5, 9, 16, and 17 is maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

This rejection is maintained and reiterated for reasons of record.

Claims 5, 9, 16, and 17 are vague and indefinite due to the unclarity of citing an abbreviation, such as PEG, PEG-MME, PEG-DME, DMSO, CHO-K1, and HEK 293. Correction is suggested by amending in of the full name in parentheses.

Applicants state these abbreviations are clear and definite to one of skill in the art and state the instant specification defines the first five abbreviations listed above. This statement is found unpersuasive as abbreviations must be followed by their full name in

parentheses unless the terms are well-known in the art. Applicants fail to support the idea that these abbreviations are well-known in the art.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-3, 5-8, 10, and 13-14 is maintained under 35 U.S.C. 102(a) as being anticipated by Hong et al. (Science, Vol. 290, 6 October 2000, pp. 150-153).

This rejection is maintained and reiterated for reasons of record.

Hong et al. disclose crystallizing human memapsin 2 (also known as beta secretase) as a complex with an inhibitor, OM99-2 (p. 151, col. 1, lines 14-16 and col. 2, first paragraph; Figure 2; and p. 153, col. 2, References and Notes #11). Hong et al. disclose preparing a purified human beta secretase in the presence of an inhibitor using 0.2 M ammonium sulfate and 0.1 Na-cacodylate (p. 153, col. 2, References and Notes #12), which are a combination of salts with a concentration of about 0.001 M to about 0.5 M as stated in claims 2, 6, and 7. Hong et al. disclose crystallizing in a solution with a

pH of 7.4 (p. 153, col. 2, References and Notes #12), which is a pH of about 5.5 and about 4.7 as stated in claims 1 and 3, respectively. Hong et al. disclose using 22.5% polyethylene glycol (PEG) (p. 153, col. 2, References and Notes #12) as stated in claim 5, which is also about 40% by weight of the solution (as stated in claim 10) and about 5% to about 50% by weight of a glycol (as stated in claims 13 and 14). Hong et al. disclose the memapsin 2/OM99-2 complex crystals contain 56% solvent content (p. 153, col. 3, lines 2-5), which is about 40% by weight organic solvent as stated in claim 8.

Thus, Hong et al. anticipate the limitations in claims 1-3, 5-8, 10, and 13-14.

The rejection of claims 1-3, 5-15, and 17 is maintained under 35 U.S.C. 102(e)(2) as being anticipated by Tang et al. (P/N 6,545,127).

This rejection is maintained and reiterated for reasons of record.

Tang et al. disclose methods for producing purified memapsin 2 (also known as human beta secretase, col. 3, line 23) and binding it to an inhibitor, OM99-2 for crystallization (col. 4, lines 8-9 and 22-33; Example 3). Tang et al. disclose crystallizing human beta secretase from a solution having a pH of 6.4 and 7.4 (col. 31, lines 1-4 and 40-43), which is a pH of about 5.5 and 4.7 as stated in claims 1 and 3, respectively. Tang et al. disclose using 0.1 M sodium cocadylate (col. 31, lines 2 and 41), and 0.2 M $(NH_4)_2SO_4$ in solution, which is a combination of salts with a concentration of about 0.001 M to about 0.5 M as stated in claims 2, 6, and 7. Tang et al. disclose using 30% and 22.5% polyethylene glycol (PEG) (col. 31, lines 1-2 and 42) as stated in claim 5, which is also about 40% by weight of the solution (as stated in claim 10) and about 5% to

about 50% by weight of a glycol (as stated in claims 13 and 14). Tang et al. disclose a beta secretase concentration near 5 mg/ml (col. 30, lines 25-28) as stated in claim 11. Tang et al. disclose an inhibitor present at a concentration of 0.3 mM (col. 7, lines 41-42), which is about 0.1 mM to about 10mM as stated in claim 12. Tang et al. disclose human beta secretase was isolated from human pancreatic cells (col. 17, lines 16-55) as stated in claim 15. Tang et al. disclose memapsin 2 from HEK 293 cells (col. 8, lines 1-2) as stated in claim 17. Tang et al. disclose human beta secretase is found in multiple tissues, including pancreas, kidney, and ovary cells (col. 18, lines 8-18). Tang et al. disclose the memapsin 2 protein is expressed in a bacterial cell (claim 1). Tang et al. disclose the inhibition of memapsin 2 by OM99-1 in a 5% DMSO solution (Figure 4A and col. 5, lines 15-17), which is up to about 40% by weight organic solvent as stated in claims 8 and 9.

Thus, Tang et al. anticipate the limitations in claims 1-3, 5-15, and 17.

Applicants state that the pH 7.4 (as disclosed by Hong et al.) and pH 6.4 and 7.4 (as disclosed by Tang et al.) are not pH about 3.5 to about 5.5, as stated in instant claim 1. This statement is found unpersuasive as the word "about" can be reasonably and broadly interpreted to be just about any pH when there is a lack of any specific guidelines directed to its exact meaning. Therefore, the pH disclosed by Hong et al. and Tang et al. fall into the broadly interpreted pH "about" recitation, as stated in instant claim 1. Therefore, these 35 USC 102 rejections are maintained.

Request for Rejoinder

The request for rejoinder is denied. Rejoinder is only granted to additional method claims when the originally examined claims are directed to a composition.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

July 13, 2004

ARDIN H. MARSCHEL 7/22/04
PRIMARY EXAMINER